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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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07/28/2004

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EXAMINER

HADDAD, MAHER M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/863,837	<b>Applicant(s)</b> CLAGETT ET AL.	
	<b>Examiner</b> Maher M. Haddad	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 4-6, drawn to a method for treating an indication resulting from an alpha 6 subunit containing integrin-mediated pathological condition in a mammal with an alpha 6 subunit containing integrin-mediated signal transduction pathway modification agent wherein the condition is an inflammation, classified in Class 424, subclass 185.1 and Class 514, subclass 17.
- II. Claim 7, drawn to a method for treating an indication resulting from an alpha 6 subunit containing integrin-mediated pathological condition in a mammal with an alpha 6 subunit containing integrin-mediated signal transduction pathway modification agent wherein the condition is a cell metastasis, classified in Class 424, subclass 185.1 and Class 514, subclass 17.
- III. Claim 8, drawn to a method for treating an indication resulting from an alpha 6 subunit containing integrin-mediated pathological condition in a mammal with an alpha 6 subunit containing integrin-mediated signal transduction pathway modification agent wherein the condition is coronary heart disease, classified in Class 424, subclass 185.1 and Class 514, subclass 17.
- IV. Claims 10-12, 15-16, 20-21 and 25-26, drawn to a method for modulating the function of an  $\alpha 6$  subunit containing integrin comprising contacting a cell having  $\alpha 6$  subunit containing integrin with an alpha 6 subunit containing integrin-mediated signal transduction pathway modification agent; classified in Class 435, subclass 7.1.
- V. Claims 13-14, 17-19 and 22-24, drawn to a cell surface complex comprising a cell surface  $\alpha 6$  integrin subunit and an alpha 6 subunit containing integrin-mediated signal transduction pathway modification agent, classified in Class 435, subclass 325.
- VI. Claim 27, drawn to a method for identifying an alpha 6 subunit containing integrin-mediated signal transduction pathway modification agent comprising attaching an alpha 6 to an affinity column and passing a suspected alpha 6 subunit containing integrin-mediated signal transduction pathway modification agent over the affinity column, classified in Class 435, subclass 7.93.

Claims 1-3, and 9 are linking claims and will be examined along with any one of elected Group I-III.

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2. Groups I-IV and VI are different methods. A method of treating, a method of modulating and a method of identifying differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

3. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

### *Species Election*

4. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

- A. If Group I-III is elected, applicant is required to elect a single specific X such as those recited in claim 2 (i.e., Tyr, Tyr-phe, Phe-Phe or Phe-Tyr), a single specific active ingredient such as those recited in claim 3 (i.e., anti-leukotrienes, beta2 antagonists or corticosteroids), and if Group I is elected a single pro-inflammatory agent such as those recited in claim 6 (such as fMLP, activated complement fragment, leukotriene B<sub>4</sub>, platelet activating factor, IL-4, IL-6, IL-8, IL-10, IL-13 or TNF $\alpha$ ). These are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.
- B. If Group IV or V is elected, applicant is required to elect a single specific X such as those recited in claims 11, 14, 16, 19, , 21, 24, or 26 (i.e., Tyr, Tyr-phe, Phe-Phe or Phe-Tyr). These are distinct species because their structures, physiochemical properties and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

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5. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

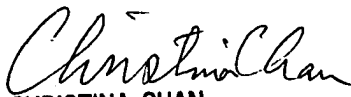
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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July 16, 2004

  
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